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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,109	01/26/2001	Allan S. Lau	4099-0003.31	8965

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/772,109	LAU ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8, 11, 12, 25, 26, 29-34, 37-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 11, 12, 25, 26, 29-34, 37-39* is/are rejected.

7)☒ Claim(s) *12, 30, 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election without traverse of Group I, with species election of the priming compound phorbol myristate acetate and the inducing agent poly I:C in Paper No. 9 is acknowledged.

Priority

This application is a CIP of application 09/657881 and the provisional application 06/152854. These prior application and provisional application do not mention CrmA or expression of CrmA in a cell line for the enhanced production of cytokines. Therefore, claims that make reference to CrmA will only be granted the priority to the filing date of the instant application which is January 26, 2001.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings have been approved by the Draftsperson.

Claim Objections

Claims 12, 30 and 38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 11, 29 and 37 are limited to the inducing agent poly I:C, from which claims 12, 30 and 38 are dependent. Claims 12, 30 and 38 comprise a Marcush group that has already been limited in the claim form which they depend.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The transitional term "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (of a cytokine. Therefore, it is not clear what is included or excluded from the claim.

Claim 3 is indefinite because the claim makes reference to a first expression vector while the clime does not contain a second expression vector. By mentioning a first expression vector the ordinary artisan would minimally expect a 2nd vector

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to encompass DNA encoding a protein effective to inhibit cell apoptosis in cells characterized by high level cytokine production. The claim is directed to encompass any and all DNAs encoding any and all proteins that inhibit any and all apoptotic mechanism. The recitation of the term DNA encoding a protein effective to inhibit cell apoptosis conveys no distinguishing information about the identity of the DNA sequence, such as its relevant structural or physical characteristic. An adequate written description of generic material requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. A description of what the genetic material does, rather that what it is, does not suffice. While the description of the ability of the protein to inhibit apoptosis may describe the protein's function, it does not describe the protein itself or the DNA encoding the protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Dixit (U.S. Pat. No. 6,159,712).

The instant invention is drawn to a human cell line a composition that comprises the CrmA coding sequences. As the cell line need only be "capable" of expressing cytokines any human cell line that has been transformed with CrmA will read on the instant claim. The burden is on applicant to show that the instant cell line would not be capable of producing cytokines.

Dixit V.M. disclose the transformation of MCF7 and BJAB cells (human derived cell line) with a vector encoding Crm-A (see examples 3, 4 and 5) The reference teaches that expression of CrmA provides resistance to the cell line against an apoptosis inducing stimulants. Therefore, the instant invention is anticipated by Dixit V.M.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 11, 12, 25, 26, 29-34 and 37-40 and rejected under 35 U.S.C. 103(a) as being unpatentable over Dixit (U.S. Pat. No. 6,159,712) and Lau et al. (U.S.Pat. No. 6,159,712).

The instant invention is drawn to a composition, a cell line (claim 1). This cell line expresses a coding sequence for an anti-apoptotic protein, specifically CrmA (claims 2). For this office action, the preamble of the product by process claims were interpreted as "a composition of matter" (which are *products*.). Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

One vector carries the CrmA sequence and the other vector carries the PKR sequence. The cell line is treated with the priming agent, phorbol myristate acetate (PMA) and an inducing agent poly I:C.

Dixit V.M. teaches the transformation of MCF7 and BJAB cells (human derived cells line) with a vector encoding Crm-A (see examples 3, 4 and 5) The reference teaches that expression of CrmA provides resistance to the cell line against an apoptosis inducing stimulants. The reference does not teach utilizing CrmA expression in a cell line for the production of cytokines.

Lau et al. teach a method of producing a cell that is able to over express cytokines wherein the cell comprises a vector containing PKR, and the cytokine expression is stimulated by induction using poly I:C and the priming agent PMA. Overexpression of PKR induced overproduction of the cytokines INF-alpha and INF-beta. The reference does not teach introducing two vectors into a cell one which encodes PKR and the other which encodes the anti apoptotic protein CrmA.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the antiapoptotic protein CrmA with the PKR cell line which is capable of overexpressing cytokines. It is well established in the art that the apoptosis induction has may stimuli, including the induction by cytokines. In an effort to express cytokines from a cell the production and release of the cytokine into the medium/supernatant will have a negative effect on the cell producing the cytokine. This is a negative feedback loop normally would function to turn off cytokine production, however, cells that keep producing cytokine will eventually die because the effect is to trigger the apoptotic event. Once too much cytokine has been produced

the cell is then stimulated to begin the path of self destruction. One having ordinary skill in the art would have been motivated to include CrmA in any cell line that is used for the expression of proteins, as taught by Lau, in order to inhibit apoptotic events. Therefore, the instant invention is obvious over of Dixit in view of Lau et al.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D. 1/27/03